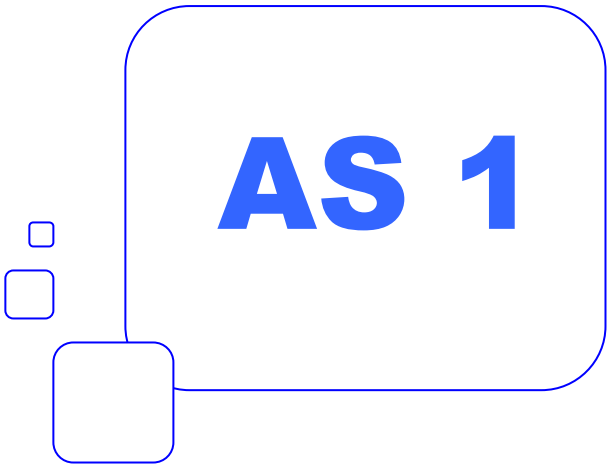
novacare gmbh

Antidecubitus –
Variable pressure system



Operating instructions

With the **novacare® AS1 Variable pressure system** you have acquired a a system for the treatment and prevention of pressure ulcers.

A good decision.

Your novacare – Team

Please read the following operating instructions carefully and observe the warning before using the system.

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1. The System / Scope of supply:

The system consists of a high-quality control unit with a membrane pump and a bed overlay with aeration. Arcs at the head and the foot end simplify the process of fixing the overlay to the existing mattress.

2. Indication / Contraindication:

Indication : Treatment and prophylaxis of pressure ulcers and decubitus

Contraindication : The system should not be applied to poly-traumatic patients, patients with fractures of the spine, pelvis and extremities or craniocerebral trauma. The attending physician has to assess indication for patients suffering from neurological deficiencies and missing body perception. Alternating resting pressure should not be applied to pain or pain-sensitive patients.In this case apply the static mode or other suitable overlays from foam or other materials, which can be found in the novacare range in ample supply.

3. Severity of Decubitus / Area of application:

The **novacare® AS1 Variable pressure system** is recommended for Decubitus up to Grade I (according to Seiler). For a higher degree of Decubitus, please use a suitable system from the **novacare®** - product range.

4. Maximum load / Patient weight:

The **novacare® AS1 Variable pressure system** has been designed for a maximum patient weight of **120 kg**. Heavier patients are better accommodated with **novacare®alternating pressure systems: APM 320+ or APM 440+.**

Please note that the existing mattress must have sufficient sturdiness due to the cell height determined by the system. Otherwise the base will absorb the rise of cells and the effect of the variable pressure system will be affected in a negative manner.

5. Technical data:

• control unit ::	weight	1.4 kg
	dimensions:	24 x 12 x 9,5 cm
	length power cord	1,7 m
	Input Rating:	AC 230-240 V / 50 Hz
		Max. 5 W
	Fuse rating:	TIAH 250 VAC 1A
	protection class:	Type BF / Klasse I
• Mattress:	weight:	1,6 kg
	dims:	200 x 90 x 6,5 cm
	material	PVC
• infl .pressure	w/o weight	30 – 110 mm Hg
• cycle		10 minutes
• surrounding conditions:		
Temperature	operation	5° ~ 40°
	Storage	-10° ~ 60°
Rel. Air humidity	operation	10 % – 95 %
	Storage	10 % – 95 %

6. Technical safety:

- Testing according to DIN EN 60601-1
- Testing according to DIN EN 60601-1-2

7. EMC:

Electric devices may interact due to electro-magnetic radiation. We recommend a safety distance of at least 1 meter distance especially for sensitive equipment.

Upon request we will provide you with a table for more detailed information.

8. This way you prepare the system for commissioning:

1. Remove the control unit from the carton and fix it at the foot end of the bed with fixing hooks.
2. Insert the power plug into an outlet of appropriate voltage.
3. Now, take the entire mattress overlay from the carton and position it on the mattress on the patient's bed.
4. The connecting tube is rolled in the folded overlay.
5. Please note that the connecting tube is at the foot end of the bed.
6. Push the overlapping parts at the head and the foot end under the mattress so that the overlay does not slide.
7. Now attach the connecting tubes to the connectors on the control unit. Push the tubes tightly onto the connectors, ensure that they are sturdy and that the tubes cannot be bent.
8. Switch on the control unit (mains switch to: "ON") and set the regulator on the control unit to the highest position.
9. Now the device starts functioning and the overlay is inflated. The process of inflation takes approx. 20 min.
10. Now set the control unit to match the weight of the patient. Now, the system is ready to be used.

9. Alternative positioning of the control unit:

The control unit of **novacare® AS1 Variable pressure system** can also be operated in a horizontal position, if a suspension is not desirable or not possible at the head end. Stoppers provided for the control unit enable secure positioning and provide adequate gap for air circulation. In any case, see to it that there is proper air circulation and that the air filter is not blocked (e.g. in case of floors with thick carpets).

10. Warning:

- Protect the control unit from humidity and direct wetness
- Keep the tubes free of bends
- Do not use the system in the proximity of a source of heat
- Pull out the power plug while moving the bed.
- Never pull the cable.
- Sharp objects must be kept away. Do not fix the overlay with inappropriate means.
- Do not use the system in the proximity of flammable gases (risk of explosion)
- Use only genuine spare parts and consumables

11. Maintenance / Inspection:

The **novacare® AS1 Variable pressure system** is considered to be a medical device according to MDD 93/42/EEC. Follow these statutory regulations while using the device.

Servicing and maintenance at regular intervals (mandatory every 2 years) iare necessary to preserve the function of **novacare® AS1 Variable pressure system.**

12. Waste Disposal:

Mattress / Overlay

The materials used for mattresses / overlays do not pose any danger for the environment. They may be disposed off with the household waste

Disposal via official waste incineration is preferred.

Control units

Control units are considered electric equipment waste. Please contact the proper waste disposal officials.

Novacare gmbh electric equipment is registered (see symbol)
WEEE – Reg.- No. DE – 89 403 200

13. Hygiene:

Systems designed for reuse must be prepared on the basis of locally valid directive, laws or regulations “for Hospital hygiene and Infection prevention“.

Already validated procedures and hygiene schedules, if any, must be applied for this preparation.

Please act according to your locally valid hygiene directives and the respective list of disinfectants for disinfecting the products and use only disinfectants listed in them. Follow the instructions for use prescribed by the respective manufacturer.

Waranty claims become null and void if inappropriate and unlisted preparations are used or are used inappropriately.

We recommend our cleaning service. Prices applicable from time to time are mentioned in the valid service price list.

- The mattress overlays of the **novacare® AS1 Variable pressure system** are not designed for re-use and hence are excluded from reprocessing.

14. Guarantee:

- The guarantee is based on statutory regulations.
- Every guarantee is excluded immediately, if the goods supplied by us are processed, handled or modified by other parties without our consent or if our operating instructions are not followed. If the seals are damaged, it will be assumed that the aforesaid activities have been carried out.
- For medical devices as understood by the MDD 93/42/EEC, whose usage (also operationsV) is subject to regular service and maintenance, a guarantee can be offered only if the service intervals prescribed by the manufacturer are adhered to.
- As far as guarantee claims are accepted and if during the subsequent inspection it is found that the damages are of wear and tear or are not subject to guarantee, then we are empowered to claim the expenses (inspection, transport costs etc.) from the customer.
- The use of parts or individual components of other systems or products or combinations thereof are not permissible. Warranty claims cease to exist for any damage resulting from this, which must be borne by the user

15. Designation / Article-No.:

- Designation *:* **novacare® AS1 Variable pressure system**
- Article No.: **99 1100**

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